

## **REMARKS**

### ***Claims***

Claims 1-29 are pending in the application.

Claims 24-29 have been withdrawn from consideration.

Claims 1-23 are rejected.

### ***Claim Rejections-35 U.S.C. 102***

The Office Action sets forth two anticipation rejections:

- 1) Claims 1-23 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Nadkarni (US 2002/0013357 Pub Date: 01/31/2002).
- 2) Claims 1-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Nadkarni (WO 01/41761 A2).

The undersigned has carefully considered the rejections and requests that they be withdrawn because the Nadkarni references fail to disclose each and every feature of the claims.

Claim 1 recites “An orally deliverable pharmaceutical composition comprising a drug of low water solubility and a pregelatinized starch having low viscosity and/or exhibiting multimodal particle size distribution.”

The Office Action details that the Nadkarni reference discloses a composition comprising valdecoxib and “National Starch 1500.” The Examiner alleges that the National Starch 1500 would inherently have low solubility or would inherently have a multimodal particle size distribution because the present application “teaches the same pregelatinized starch in the tablet.”

To clarify, the undersigned notes that the present application refers to “Colorcon Starch 1500” in the examples instead of “National Starch 1500.”

Further, the alleged inherent properties of “National Starch 1500” are not supported by the data appearing in the application. Reference is made to the examples appearing in the application on pages 21-25. Example 2 provides details regarding different batches of tablets that were made using 11 different lots of “Colorcon Starch 1500.” Even though all the tablets were made with “Colorcon Starch 1500,” not all of the tablets had the same dissolution performance. Further testing was done and only some of the lots of “Colorcon Starch 1500” were determined to be of low viscosity, which was found to have a correlation with dissolution performance. Based on these results, it can not be assumed that all types of a pregelatinized starch would have low viscosity because it does not appear to be a common feature. Therefore,

low viscosity should not be considered an inherent property. The same reasoning applies to multimodal particle size distribution versus unimodal particle distribution. See, for example, page 24 of the application.

Due to the foregoing, the undersigned asserts that low viscosity and multimodal particle size distribution are not disclosed explicitly or inherently in the cited reference. Therefore, independent claim 1 and dependent claims 2-23 should not be rejected based on the Nadkarni references.

#### Rejoinder

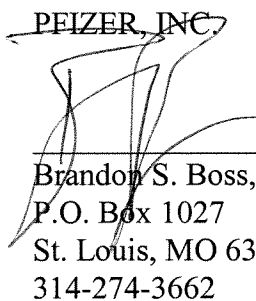
Rejoinder of claims 24-29 is requested upon allowance of composition claims 1-23.

#### ***Conclusion***

The Examiner is invited to contact the undersigned attorney should any issues remain unresolved. If any additional fees are due in connection with the filing of this response, such as fees under 37 C.F.R. §§ 1.16 or 1.17, please charge the fees to Deposit Account No. 19-1025. Any overpayment can be credited to Deposit Account No. 19-1025.

Respectfully submitted,

~~PEIZER, INC.~~

A handwritten signature in black ink, appearing to read 'Brandon S. Boss', is written over a horizontal line. The signature is stylized and overlaps the text below it.

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